REMARKS

Claims 1-9, 11-19, and 23-39 are pending. Claims 10 and 20-22 have been cancelled. Claims 26-39 have been added. No claims have been allowed.

The Examiner's attention is respectfully directed toward commonly-owned, co-pending U.S. Patent Application Serial No. 11/203,986, in which the Examiner has applied similar art as in the present application.

Applicants have amended the specification by deleting ASTM Standard F538 and substituting ASTM F138. Applicants submit that there is no ASTM F538 in existence and that the change has been made to clarify the specification. No new matter has been added. Applicants attach hereto copies of the recited ASTM Standards F90, F138, F562, and F2063. Applicants also submit that while the Standards are updated periodically, the basic medical compositions recited in the Standards have not changed since their creation. If those basic chemical compositions had changed, a new Standard with a new number would have been created.

Responsive to the rejection of Claims 5 and 17 under 35 U.S.C. §112, second paragraph, Applicants have deleted reference to ASTM Standard F562 and have replaced same with --a colbalt-nickel-chromium alloy--.

The Examiner rejected Claims 1, 11, 12, 18, and 20-25 under 35 U.S.C. 102(b) as anticipated by U.S. Patent 5,283,232 to Kohno ("Kohno et al. '232").

Kohno et al. '232 relates to a method for producing oxide superconducting composite wires. Superconductivity, as is well known, is a characteristic of certain metals at certain very low temperatures, such as for instance, 91 K (-180° C). Additionally, the oxide superconducting composite wire, as discussed at col. 2, beginning at line 7 of Kohno et al. '232, defines the term oxide superconducting material as a material containing elements comprising an oxide superconductor which contains, for example, alkali earth metal elements, elements in Group IIIa of the Periodic Table, and copper oxides. Alkali earth metal elements may include Be, Sr, Mg, Ca, Ba, and Ra. Such alkali earth metal elements may be employed in the form of a powder of a compound such as a carbonate, oxide, chloride, sulfide, or fluoride, or an alloy powder. As shown in Fig. 2 of Kohno et al. '232, a layer 22 is formed of such an oxide superconducting powder material (*see* column 5, lines 34 and 35). Further, as shown in Fig. 5, element 31 is

formed of such a molded product.

With respect to the presently amended claims, Kohno et al. '232 is silent as to the biocompatibility of the disclosed powder and metal of which the wire is composed. Applicants respectfully submit that the substances recited in Kohno et al. '232 are not biocompatible substances suitable for an implantable medical device, as are the biocompatible metals recited in the presently amended claims. Furthermore, Applicants respectfully submit that one skilled in the art of biocompatible medical grade wire would not look to the superconducting wire art of Kohno et al. '232 and specifically would not find it obvious, even if such art had been brought to such a person's attention, to arrive at Applicants' invention.

For the foregoing reasons, Applicants submit that none of the pending claims are either anticipated by, nor would be obvious in view of, Kohno et al. '232.

The Examiner rejected Claims 1-10, 12-17, and 19 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 2,050,298 to Everett ("Everett '298") in view of U.S. Patent No. 5,483,022 to Mar ("Mar '022").

Everett '298 discloses a metal reducing method for reducing the diameter of a plurality of wires by a drawing process, for example. Initially, Everett '298 teaches away from the method shown in Figs. 1 and 2 and discussed at page 1, right column, lines 22-33 therein, in which a number of wires 10 are encased in tube 11, which is then drawn down as shown in Fig. 2 in a manner in which the cross-sections of the individual wires 10 become distorted.

Rather, Everett '298 teaches that it is desirable to reduce the diameters of wires 10 without distorting the cross-sections of the wires 10. To accomplish this, Everett '298 teaches a method for reducing the diameter of a plurality of wires by placing same inside a tube 11 along with a "matrix" of the type set forth at page 1, left column, lines 22-46, such as a packing material 12 shown in Fig. 3. In this manner, the reduction in diameter of the tube 11 by drawing is effectively transferred through packing material 12 to wires 10 to reduce the diameter thereof without distorting the cross-sections of the individual wires 10. Then, after the foregoing construct has been drawn, tube 11 is removed to thereby access the individual wires 10 for a later application.

Amended independent Claim 1 calls for a metallic lead including an outer shell made of a first biocompatible metal; a plurality of wire elements disposed within the shell, each of the wire elements comprising a metallic shell made of a second biocompatible metal, the metallic shell

filled with a third biocompatible metal, the plurality of wire elements being compacted together whereby substantially no voids exist within the outer shell; and an insulation layer disposed around the outer shell.

Applicants respectfully submit that amended independent Claim 1 cannot be obvious over Everett '298, either by itself or in combination with any other reference because, first, Everett '298 teaches away from a metallic wire lead having an outer shell made of a first biocompatible metal, and a plurality of wire elements disposed within the shell whereby substantially no voids exist within the outer shell. As discussed above, Everett '298 specifically teaches away from the drawn construct shown in Fig. 2 thereof, in which an outer shell containing a number of wire elements is drawn in a manner in which the cross-sections of the individual wires is distorted.

Second, Everett '298 fails to disclose, and teaches away from, a metallic wire lead including an outer shell made of a first biocompatible metal, a plurality of wire elements disposed within the shell each including a metallic shell made of a second biocompatible metal, the metallic shell filled with a third biocompatible metal. Specifically, Everett '298 fails to teach the use of biocompatible metals and, in particular, an outer shell made of a biocompatible metal. Further, one of ordinary skill in the art would not use a biocompatible metal for outer tube 11 in the Everett '298 method because the outer tube 11 is removed after drawing to access the individual wires 10 of a reduced diameter within the drawn tube 11. In this manner, the outer tube 11 of Everett '298 is only a temporary encasing structure allowing the entire construct to be drawn to thereby reduce the diameters of the individual wires 10. After drawing, outer tube 11 is removed. Therefore, there is no incentive whatsoever for one of ordinary skill in the art to form outer tube 11 of a biocompatible metal, as opposed to the other materials for outer tube 11 that are disclosed by Everett '298, namely, such as high carbon steel (page 2, right column, line 64).

Further, Everett '298 fails to disclose, and teaches away from, an insulation layer disposed around the outer shell. As discussed above, because outer tube 11 is removed after the drawing process of Everett '298, one of ordinary skill in the art would have no incentive whatsoever to form an insulation layer around outer tube 11.

For the foregoing reasons, Applicants respectfully submit that amended independent Claim 1, as well as the claims which depend therefrom, cannot be obvious over Everett '298, either by itself or in combination with any other reference.

Amended independent Claim 12 calls for a method of making a lead, said method including the steps of providing a first tube made of a first biocompatible metal, the first tube having a first diameter; forming a plurality of wire elements into a bundle, the wire elements each comprising a metallic shell made of a second biocompatible metal, the metallic shell filled with a third biocompatible metal; inserting the bundle into the first tube to form an assembly; thereafter drawing the assembly down to form a wire with a second diameter less than the first diameter; and applying an insulation layer to the assembly.

Amended independent Claim 23 calls for a method of making a composite wire, said method including the steps of providing a first tube made of a first biocompatible metal, the first tube having a first diameter; forming a plurality of wire elements into a bundle, at least one of the wire elements made of a second biocompatible metal, at least one of the wire elements made of a third biocompatible metal; twisting the bundle; inserting the bundle into the first tube to form an assembly; and thereafter drawing the assembly down to form a wire having a second diameter.

Similar to the reasons discussed above with respect to independent Claim 1, Applicants submit that amended independent Claims 12 and 23, as well as the claims that depend therefrom, cannot be obvious over Everett '298, either by itself or in combination with any other reference.

Namely, Everett '298 fails to disclose, and teaches away from, the use of biocompatible metals for an outer tube, as called for in amended independent Claims 12 and 23.

Second, Everett '298 fails to disclose the step of twisting the bundle of wires prior to inserting the bundle into a tube and thereafter drawing the assembly, as called for in independent Claim 23 and dependent Claim 19 which depends from independent Claim 12. One of ordinary skill in the art would know from the teachings of Everett '298 that there would be no reason for twisting wires 10 before inserting them into tube 11 followed by drawing tube 11. First of all, twisting wires 10 of Everett '298 prior to insertion into tube 11 would not be necessary to affect a reduction in the diameters of wires 10 by drawing and second, twisting wires 10 prior to inserting same within tube 11 would allow much less room for matrix 12 to occupy the space between the individual wires 10, which is critical to the method of Everett '298 by which the individual wires 10 are drawn to reduced diameters. Further, the Examiner is respectfully directed to note that the embodiment of Fig. 6 of Everett '298 (*see* page 1, left column, lines 47-54 and page 2, left column, lines 42-61), in which a metal wire or strip 14 may be wrapped

helically around the bundle of wires 10, is used to facilitate separation of the wires, and is quite different from twisting wires 10 themselves. Finally, as set forth at page 3, left column, lines 25-36, Everett '298 discloses twisting the individual wires 10 only after they have been drawn to effect a reduction in diameter thereof, presumably in view of the foregoing considerations.

Further, Everett '298 fails to disclose, and teaches away from, the step of applying an insulation layer to an assembly formed of an outer tube having a bundle of wires therewithin, as called for in independent Claim 12 and in dependent Claim 28, which depends from independent Claim 23.

Finally, for at least the reasons discussed above, neither Kohno et al. '232 nor Everett '298 disclose a metallic wire comprising an outer shell comprising platinum, and a plurality of first wire elements disposed within said shell, at least one said first wire elements being a tube comprising a cobalt-nickel-chromium alloy filled with a third metal comprising silver, as called for in new independent Claim 30, nor the subject matter of Claims 31-39 which depend therefrom.

In the event Applicants have overlooked the need for an extension of time, payment of fee, or additional payment of fee, Applicants hereby petition therefore and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels LLP.

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Should the Examiner have any questions, the Examiner is respectfully invited to telephone the undersigned at 260-460-1741.

Respectfully submitted,

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